

Appln. No. 09/744,804
Amdt. dated May 23, 2005
Reply to Office Action of January 27, 2005

REMARKS

The Office Action and the cited and applied reference have been carefully reviewed. Claims 16 and 55-57 are allowed. Claim 58 also presently appears in this application and defines patentable subject matter warranting its allowance. Reconsideration and allowance are hereby respectfully solicited.

Claim 19 has been objected to under 37 CFR 1.75(c) as being of improper dependent form for failing to further limit the subject matter of a previous claim because the examiner asserts that claims 1 and 19 are both limited to SEQ ID NO:78 drawn to human Lactadherin (BA-46) and, therefore, claim 19 does not further limit the base claim. This objection is made moot by the cancellation of claim 19 without prejudice.

Claims 1, 19, 21, 23, 44, and 58 have been rejected under 35 U.S.C. §112, first paragraph, because the specification while being enabling for the SEQ ID NOs:35-41, does not reasonably provide enablement for other peptides consisting of 9 or 10 contiguous amino acid residues in the sequence of SEQ ID NO:78. The examiner has then detailed the lack of enablement rejection and cited again US Pat. 5,840,839 to stress that finding a peptide that binds to a MHC molecule and stimulates immune response is not a trivial matter. This rejection is respectfully traversed insofar as, of the rejected claims, only claim 58 is still pending.

Contrary to the examiner's assertion and as previously argued, the specification discloses in the section "Material and Methods", page 24, subsection "Scoring of HLA-A2.1 binding peptides", as follows: "Protein sequences were screened for MHC binding by a HLA Peptide Binding Predictions software approachable through a worldwide web interface (see also reference 82). This software, based on

accumulated data, scores every possible peptide in the protein for possible binding to MHC according to the contribution of every amino acid in the peptide. Theoretical binding scores represent calculated half-life of the HLA-A2.1-peptide complex". (emphasis added)

The peptides predicted to bind with high affinity to the MHC molecule are then synthesized according to the method for peptide synthesis as disclosed in the present specification on page 24, first paragraph. Actual binding to HhD of the peptides is measured according to the method of measurement of peptide binding by stabilization of cell surface MHC, disclosed on page 25, first paragraph. Finally, *in vitro* cytotoxicity assays are performed as described on page 25, last paragraph.

As stated before, the seven BA-46 peptides that bind to HLA-A2, shown in Table 7 of the instant specification, are those that have shown a higher affinity using the prediction program described. However, other peptides with a different affinity can be predicted and synthesized or modified and used for the purpose of the present invention. Moreover, by using other available HLA Peptide Binding Prediction software, restriction to other HLA molecules can be carried out and the peptides, obtained by running said software, can be synthesized or modified and tested, all according to the procedures described in the instant specification. Therefore, those of skill in the art are enabled for the scope of the presently claimed invention without undue experimentation.

Reconsideration and withdrawal of this rejection are therefore respectfully requested.

Claims 1, 19, 21, 23, and 44 have been rejected under 35 U.S.C. §102(b) as being anticipated by Gaagler et al., *J. Exp. Med.*

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179:921-930 (1994). This rejection is made moot by the cancellation without prejudice of the rejected claims.

In view of the above, the claims comply with 35 U.S.C. §112 and define patentable subject matter warranting their allowance. Favorable consideration and early allowance are earnestly urged. To expedite prosecution, the examiner is specifically urged to contact the undersigned at the telephone number below if there are any outstanding issues that need to be resolved in order to place this application in condition for allowance.

In view of the above, the claims comply with 35 U.S.C. §112 and define patentable subject matter warranting their allowance. Favorable consideration and early allowance are earnestly urged.

Respectfully submitted,

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